D. Subpart D -- Coverage and Benefits: General Provisions

1. Basis, scope, and applicability (§457.401).

As proposed, this subpart interprets and implements section 2102(a)(7) of the Act, which requires that States make assurances relating to certain types of care, including assuring quality and appropriateness of care and access to covered services; section 2103 of the Act, which outlines coverage requirements for children's health benefits; section 2109 of the Act, which describes the relation of the SCHIP program to other laws; section 2110(a), which describes child health assistance; and certain provisions of section 2110(c)(6) of the Act, which contains definitions applicable to this subpart. The requirements of this subpart apply to child health assistance provided under a separate child health program and do not apply to Medicaid expansion programs even when funding is based on the enhanced Federal medical assistance percentage. We received no comments on this section and have retained the language in this final rule.

2. Child health assistance and other definitions (§457.402).

Proposed §457.402 set forth the definition of child health assistance as specified in section 2110(a) of the Act. We did not propose to include any additional services in the definition of child health assistance or attempt to further define the services set forth in the Act in order to give States flexibility

to provide these services as intended under the statute. Accordingly, we proposed that the term “child health assistance” means payment for part or all of the cost of health benefits coverage provided to targeted low-income children through any method described in §457.410 for any of the following services as specified in the statute:

- Inpatient hospital services.
- Outpatient hospital services.
- Physician services and surgical services.
- Clinic services (including health center services) and other ambulatory health care services.
- Prescription drugs and biologicals and the administration of such drugs and biologicals, only if such drugs and biologicals are not furnished for the purpose of causing, or assisting in causing, the death, suicide, euthanasia, or mercy killing of a person.
- Over-the-counter medications.
- Laboratory and radiological services.
- Prenatal care and prepregnancy family planning services and supplies.
- Inpatient mental health services, other than inpatient substance abuse treatment services and residential substance abuse treatment services, but including services furnished in a State-operated mental hospital and including residential or other

24-hour therapeutically planned structured services.

- Outpatient mental health services, other than outpatient substance abuse treatment services, but including services furnished in a State-operated mental hospital and including community-based services.
- Durable medical equipment and other medically related or remedial devices (such as prosthetic devices, implants, eyeglasses, hearing aids, dental devices and adaptive devices).
- Disposable medical supplies.
- Home and community-based health care services and related supportive services (such as home health nursing services, personal care, assistance with activities of daily living, chore services, day care services, respite care services, training for family members and minor modification to the home.)
- Nursing care services (such as nurse practitioner services, nurse midwife services, advanced practice nurse services, private duty nursing, pediatric nurse services and respiratory care services) in a home, school, or other setting.
- Abortion only if necessary to save the life of the mother or if the pregnancy is the result of rape or incest.
- Dental services.
- Inpatient substance abuse treatment services and residential substance abuse treatment services.
- Outpatient substance abuse treatment services.

- Case management services.
- Care coordination services.
- Physical therapy, occupational therapy, and services for individuals with speech, hearing and language disorders.
- Hospice care.
- Any other medical, diagnostic, screening, preventive, restorative, remedial, therapeutic, or rehabilitative services (whether in a facility, home, school, or other setting) if recognized by State law and only if the service is prescribed by or furnished by a physician or other licensed or registered practitioner within the scope of practice as defined by State law; performed under the general supervision or at the direction of a physician; or furnished by a health care facility that is operated by a State or local government or is licensed under State law and operating within the scope of the license.
- Premiums for private health care insurance coverage.
- Medical transportation.
- Enabling services (such as transportation, translation, and outreach services) only if designed to increase the accessibility of primary and preventive health care services for eligible low-income individuals.
- Any other health care services or items specified by the Secretary and not excluded under this subchapter.

We proposed to define the terms “emergency medical

condition," "emergency services, and "post-stabilization services" to give full meaning to the statutory requirement at section 2102(a)(7)(B) of the Act that States assure access to emergency services consistent with the President's directive to Federal agencies to address the *Consumer Bill of Rights and Responsibilities*, which includes the right to access to emergency services. We proposed to define the term "emergency medical condition" as a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, with an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in --

- Serious jeopardy to the health of the individual or, in the case of a pregnant woman, the health of a woman or her unborn child;
- Serious impairment of bodily function; or
- Serious dysfunction of any bodily organ or part.

We proposed to define the term "emergency services" as covered inpatient or outpatient services that are furnished by any provider qualified to furnish emergency services without requirement for prior authorization and needed to evaluate or stabilize an emergency medical condition. Because these terms are used throughout the regulation, we have moved the definitions of "emergency services" and "emergency medical condition" to

§457.10, the overall definitions section. The comments and responses related to these definitions are addressed in §457.10.

We proposed to define "post-stabilization services" to mean covered medically necessary non-emergency services furnished to an enrollee after he or she is stabilized related to the emergency medical condition.

We proposed to define "health benefits coverage" as an arrangement under which enrolled individuals are protected from some or all liability for the cost of specified health care services.

Comment: A commenter agreed that our definition of "child health assistance" is appropriate and considered the specific identification of advanced practice nursing services at §457.402(a)(14) to be crucial to ensuring that children in fact receive the care to which they are entitled by statute.

Response: We appreciate the commenter's support for our definition. The proposed regulation set forth the definition of child health assistance as specified in section 2110(a) of the Act. The provision of advanced practice nursing services is specifically identified in that section as a coverable service.

Comment: One commenter questioned why well-baby care, well-child care and immunizations are not explicitly included in the list of definitions. These benefits are the cornerstone of pediatric care and the commenter indicated that it is important

that they are explicitly included wherever appropriate.

Response: Section 2102(a)(7) of the Act provides the authority for requiring that well-baby and well-child care and immunizations be included under every State plan. Well-baby and well-child care and immunizations were not specified in the statutory definition of "child health assistance" at section 2110 of the Act, although they clearly fall within this definition of "child health assistance." Additionally, well-baby and well-child care are not separate categories of services, but can include services that are in any or all of the separately defined categories of services. However, because these terms are used throughout the regulation we have included them in the definitions at §457.10. These services are also discussed at §§457.410 and 457.520.

Comment: One commenter was concerned about the definition of post-stabilization services and the language in the preamble stating that HCFA would expect States and their contractors to treat post-stabilization services in the same manner as required for the Medicare and Medicaid programs, while recognizing that not all such services would be necessarily covered by the State for purposes of SCHIP.

While the commenter did not object to permitting States to apply to separate child health programs an interpretation of post-stabilization services that is the same as that under

Medicaid and Medicare, they believed that HCFA should give States flexibility to treat the coverage of post-stabilization services differently depending upon the structure of the State program. A State that designs its separate child health program to mirror its Medicaid program would want to retain the same interpretation for both programs. However, a State that models its program after commercial coverage would want to adopt an interpretation that is applicable to commercial coverage that is offered by MCEs. Such flexibility would be particularly important if the State decides to provide coverage to SCHIP eligibles by purchasing coverage from employer group health plans to cover children. In those cases, the emergency services requirement should parallel those applicable to the employer's group health insurance coverage. The commenter recommended that the proposed regulation be revised to reflect this needed flexibility.

To the extent that States adopt or HCFA requires use of the interpretation of the post-stabilization services requirements applicable under the Medicaid and Medicare programs, the commenter reiterated its comments on the Medicaid managed care notice of proposed rulemaking and the interim final Medicare+Choice regulation. The issue of concern to this commenter was whether the requirement that Managed Care Entities (MCEs) respond to requests for approval of post-stabilization services within one hour is reasonable.

The commenter expressed considerable concern about requirements for post-stabilization care for MCEs, particularly the requirement that MCEs respond to requests for approval of post-stabilization care within one hour. The commenter suggested conditions to moderate the effect of this requirement.

Response: We agree with the commenter that States should have the flexibility to treat coverage of post-stabilization services differently depending on the health benefits coverage elected by the State. The preamble to the proposed rule may have been misleading by appearing to require the provision of post-stabilization services under a separate child health program, therefore, we have removed the references to post-stabilization services, covered or otherwise, from the final rule. We hope that this will minimize confusion.

Comment: Several commenters on proposed §457.995 had other concerns regarding the provision of post-stabilization services for individuals in managed care. These commenters expressed concern that managed care organizations should be allowed to control their own networks. A payment network needs the flexibility to require a patient to be transferred to an appropriate facility within its network after the emergency has been stabilized. According to these commenters, this regulation takes the control of non-emergency services away from the network and gives it to a non-network provider and could defeat the

concept of managed care. The commenters believed that when emergency care is provided outside of the MCE network, it is usual and customary for the patient to be transferred to an appropriate facility within their MCE network for required post-stabilization services.

Response: Proposed §457.995(d), the provision in the overview of beneficiary rights referencing post-stabilization services, has been removed from the regulations text along with the rest of §457.995 for the sake of clarity and consistency.

Comment: One commenter noted that the preamble to the proposed rule indicates that HCFA considered defining transportation to include coverage for transportation to more than primary and preventive health care as stated in the law. However, the commenter noted that HCFA decided to leave the option of establishing the definition to the States. The commenter regarded transportation as including urgent and emergent care and that transfer/transport to a hospital or health facility for urgent and emergent care should be included in a child's health benefit package.

Response: Under the list of services in section 2110(a) of the Act and §457.402 of this final regulation, transportation is mentioned in two different items: (26) medical transportation and (27) enabling services (such as transportation, . . .). While coverage for transportation services is not required, almost

every State already provides coverage for emergency transportation under its State plan. Therefore, we do not see lack of coverage of this service as a problem and will not further define transportation services.

Comment: We received several comments on proposed §457.402(a)(26), redesignated as paragraph (27), which provides for enabling services (such as transportation, translation, and outreach services) only if designed to increase the accessibility of primary and preventive health care services for eligible low-income individuals. One commenter indicated that States should be required to fund community health centers to provide outreach activities and enabling services such as translation and transportation (rather than, or in addition to, outreach costs that are reimbursed under administrative accounts).

Several other commenters indicated that the phrase “outreach services . . . only if designed to increase the accessibility of primary and preventive health care services for eligible low-income individuals” is ambiguous and requested clarification. They noted that this phrase could be read to permit a State to pay primary health providers such as health centers to conduct outreach activities to find eligible children as part of their overall child health assistance services (rather than, or in addition to, outreach costs that are reimbursed under administrative accounts). The commenter noted that this is

important because the SCHIP statute caps States' overall administrative costs and thus has been viewed as providing insufficient funds to support the types of outreach efforts that experts say are necessary to find eligible children. To the extent that the phrase "outreach . . . to eligible low-income individuals" is interpreted as the identification of eligible children, then this represents an important option for States and health centers. States could build outreach funds into their payments to SCHIP primary care providers, along with funding for other forms of enabling services, such as translation and transportation costs.

In the context of payment to primary health care providers, one commenter also indicated that States could build funds for outreach and enabling services into their payments to SCHIP primary care providers. The commenter indicated that community clinics and health centers in its State are encountering difficulties and confusion when being audited for purposes of receiving cost-based reimbursement from the State.

Response: In developing their State plans, States determine their own providers. We cannot require that community health centers be funded to provide outreach and enabling activities. The language of proposed §457.402(a)(26) was taken directly from the language at section 2110(a)(27) of the Act. Enabling services, including outreach to assist children's access to

primary and preventive care, are one of the types of services States may choose to provide as part of the "child health assistance" that meets the requirements of section 2103 of the Act. We note that under the terms of section 2110(a) and 2110(a)(27), these services must be delivered to "targeted low-income children" who are "eligible" for "child health assistance" under the State plan. Therefore, when enabling services are provided as part of the health benefits coverage for children who are found eligible and enrolled, these services would not be subject to the 10 percent cap on administrative expenditures under 2105(c) of the Act. However, outreach initiatives to potentially eligible children are subject to the 10 percent cap in accordance with section 2105(a)(2)(C) of the Act. We do not understand the commenter's specific concerns regarding difficulties in receiving cost-based reimbursement in the State's community clinics and health centers so we are unable to respond to this comment. (We note that, in this final rule, we have listed physician services and surgical services (proposed §457.402(a)(3)) separately as paragraphs (3) and (4), respectively. As a result, the services listed at paragraphs (a)(4) through (a)(27) have been redesignated as paragraphs(5) through (28). Enabling services are now listed at paragraph (27).)

Comment: One commenter noted its belief that the preamble

should encourage States, in selecting among benefits to cover, to consider the needs of different age groups, their varying health status and patterns of morbidity and mortality, the impact of developmental states on their needs and their patterns of utilization. They observe, for example, that coverage of over-the-counter medications may be of particular benefit to adolescents. Also, eating disorders are more common among adolescents than younger children, and family planning services should include a choice among all contraceptive methods and options.

Response: We concur with the commenter and encourage States to consider the populations they are serving and the needs of different age groups when designing their benefit package States need only cover medically necessary and appropriate services, but the statute at section 2102(a)(7) and the regulations at §457.495, specifically require States to specify the methods they will use to assure appropriate care.

Comment: Two commenters noted that the language on services in the proposed rule was set out identically to the language in the statute. The commenters were concerned that the definition of both inpatient and outpatient mental health services excludes substance abuse treatment services, which are listed separately in the statute and the regulation. One commenter was concerned that this separation means only that payment *may* be made for

these services, not that payment *shall* be made for these services and believes that States should be encouraged to consider their inclusion for comprehensive treatment for adolescents with co-occurring mental and substance abuse disorders.

Similarly, another commenter is concerned that the separation of outpatient substance abuse treatment services may allow the provision of outpatient mental health services but not the provision of outpatient substance abuse services, but would include services furnished in a State-operated mental hospital and community-based services. The commenters indicated that substance abuse impacts a significant number of children in their States and rather than removing this important benefit, they recommended that the regulations need to encourage and even highlight the importance of offering this benefit.

The commenter noted that while the listings for mental health inpatient and outpatient services in the regulations specifically exclude substance abuse services, these services are listed separately from inpatient and outpatient mental health services. The commenter called attention to this because of the high incidence of co-occurring disorders among adolescents with presenting symptoms of one or the other. Even though these services lack the 75 percent actuarial measure required when mental health services (and/or prescription drugs, vision and hearing services) are included, States should consider their

inclusion for comprehensive treatment of adolescents with co-occurring mental and substance abuse disorders.

Response: We appreciate the commenter's view about the importance of respite care services. As we have indicated previously, the proposed rule at §457.402 mirrors the language of section 2110(a). Therefore, inpatient mental health services and inpatient substance abuse treatment services, as well as outpatient mental health services, and outpatient substance abuse treatment services are listed separately in the regulation as they were in the statute. States choose to cover services from the list of services under the definition of "child health assistance" when they select a health benefits coverage option under §457.410. The statute supports mandating that only three types of services, well-baby and well-child services, immunizations, and emergency services, be included in all SCHIP plans regardless of the type of health benefits coverage chosen. HCFA encourages States to provide inpatient and outpatient substance abuse services. A State may choose to provide inpatient mental health and substance abuse services; however the statute provides flexibility for the States in determining the scope of covered benefits.

We do, however, call the commenter's attention to the requirement in §457.120 of the regulations for ongoing public input in the development and implementation of SCHIP plans.

Comments and concerns about benefits and coverage should be directed to and taken under consideration by the State SCHIP agency. We encourage States to consider the populations they are serving and the needs of different age groups when designing their benefit packages.

Comment: One commenter particularly noted the inclusion in §457.402 of "respite care services and training for family members," which are especially relevant to families with children with severe and persistent mental illness or brain disorders. The commenter stated that it would appreciate attention being called to these services' eligibility for coverage and relevance in plans that offer supplemental mental health services, in addition to other services, "i.e., respite care, advanced practice nurse services, and pediatric nurse services . . . in a home, school or other setting."

Response: As we have indicated previously, States that implement separate child health programs are given broad flexibility to design their benefit packages. We encourage commenters to work with their States to assure that valuable health care services are made available to children to the extent possible in each State.

Comment: One commenter recommended §457.402 be deleted because the statute provides States with flexibility in the design of the SCHIP benefit package and this section implies that

coverage for certain services should be available under SCHIP when it is not required by statute and may not be included in the state-designed benefit package.

Response: Section 2110 of the Act allows for payment for part or all of the cost of health benefits coverage (as defined at §457.10) for any services listed in section 2110(a) of the Act as implemented in §457.402. These provisions do not indicate that States must provide all of these services; rather, they list the array of services for which payment may be made. We disagree with the commenter and have not deleted this section from the proposed rule.

3. Health benefits coverage options (§457.410).

Under the authority of section 2103 of the Act, at proposed §457.410, we listed the four options a State has for obtaining health benefits coverage for eligible children. Specifically, we proposed that States may choose to provide benchmark coverage, benchmark-equivalent coverage, existing comprehensive State-based coverage, or Secretary-approved coverage. These four options are described at §§457.420 through 457.450.

Based on the authority of section 2102(a)(7) of the Act, we also proposed at §457.410(b) to require that a State must obtain coverage for well-baby and well-child care, immunizations in accordance with the recommendations of the Advisory Committee on Immunization Practices (ACIP), and emergency services. We noted

that the State must cover these services even if coverage for these services is not generally included in the health benefits coverage option selected by the State.

We proposed to define well-baby and well-child care for purposes of cost sharing at proposed §457.520(b), but we proposed to allow States to define well-baby and well-child care for coverage purposes. We encouraged States, however, to adopt the benefits and periodicity schedules recommended by a medical or professional organization involved in child health care when defining well-baby and well-child care coverage.

Comment: Two commenters supported the requirement that States use the ACIP schedule for immunizations under their separate child health programs. However, many commenters disagreed with the proposal that States be required to follow the immunization schedule of the ACIP, particularly because they are not allowed to participate in the VFC program. It was suggested that States should be able to adopt their own immunization periodicity schedules. One commenter suggested that we rewrite this section to require “immunizations as medically necessary” rather than require that immunizations be provided according to the ACIP schedule. Several commenters suggested that a State that utilizes existing commercial health plans may not use any particular standard immunization schedule or may follow other professional standards. One commenter mentioned that its State

uses another standard, the recommended childhood immunization schedule jointly adopted by the American Academy of Pediatrics (AAP), the ACIP, and the American Academy of Family Physicians (AAFP).

Response: Section 2102(a)(7)(A) requires that a State child health plan include a description of a State's methods to assure the quality and appropriateness of care, "particularly with respect to . . . immunizations provided under the plan." In order to ensure that all SCHIP children are appropriately immunized, States should use a uniform, nationally recognized schedule of immunizations. The ACIP schedule referred to in the proposed rule is a harmonized schedule approved by the ACIP, the AAP, and the AAFP. It is referred to as the "Childhood Immunization Schedule of the United States." The AAP and AAFP no longer develop and maintain separate immunization schedules but rather use the harmonized ACIP schedule. This ACIP schedule is the same as the standard referenced by one of the commenters as the schedule relied on by its State. States should use the ACIP schedule because it reflects the current standards of these pediatric speciality providers who are the recognized authorities in childhood immunizations.

Comment: Several commenters expressed their belief that requiring SCHIP programs to use the ACIP immunization schedule is overly prescriptive and has no basis in the statute. According

to one commenter, the only statutory limit on States' discretion is found in section 2102(a)(7)(A), which indicates that the State plan must include a description of the methods used to assure the quality and appropriateness of care, particularly with respect to immunizations. The commenter cited Executive Order 13132 on federalism, and asserted that, consistent with that authority, States should be permitted to select their own immunization standards unless HCFA can demonstrate both a need for a federal standard and that it has considered alternatives that would preserve the States' prerogatives.

Response: As described in the response to the previous comment, section 2102(a)(7)(A) of the Act provided authority to require immunizations in accordance with the recommendations of ACIP. Therefore, the requirement to use the ACIP schedule is not a violation of E.O. 13132. The ACIP schedule is a national standard developed and approved by three national medical organizations involved in child health care services, the ACIP, the AAP and the AAFP. These organizations use the harmonized ACIP immunization schedule and no longer use separate immunization schedules. Requiring coverage for appropriate immunizations at appropriate times, as the ACIP schedule recommends, does not place undue burden on States given the importance of childhood immunizations. In fact, it releases States from the burden of having to develop or choose their own

individual schedules and establish the adequacy of those schedules with respect to title XXI statutory requirements. Given the unique nature of infectious diseases, and the mobility of the population across State lines, it is necessary to require a uniform approach to immunizing children across all States.

Comment: One commenter believed the 90-day requirement explained in the preamble to the proposed rule for States to adhere to any changes in the ACIP recommendations is inappropriate. The current policy is that States have 90 days from the publication of the revised ACIP schedule in the Morbidity and Mortality Weekly Report to implement those changes in their programs. The commenter believed that this requirement fails to recognize the realities of effectuating such a change in benefits. States should have until the end of the current contract period but in no case longer than one year to comply with any ACIP changes.

Response: It is essential for children to receive vaccines according to the most current ACIP recommendations in order to maximize children’s health, minimize morbidity and mortality, and reduce costs of treating preventable disease. In addition, good public health policy argues for consistent adoption of vaccine recommendations across all States in order to minimize the potential for transmission of communicable disease.

Comment: One commenter expressed its opinion on the

importance of children in separate child health programs receiving all necessary immunizations and of vaccines being incorporated in all benefit packages. The commenter also suggested two ways that States may provide immunizations through their SCHIP programs without opening up the VFC program: 1) a State may add on payments for the provision of immunizations through participating MCEs; or 2) the State may declare that children enrolled under a separate child health program are State vaccine eligible. The State may then purchase the vaccines at the Federal contract price and distribute them to SCHIP providers as it currently does for Medicaid providers. The commenter stated that expenditures under either of these options would be matched by the Federal government at the SCHIP enhanced matching rate and would not count as administrative expenditures under the 10 percent cap. Additionally, the commenter believed that the State should require that plan contracts include provisions that require plans to provide and cover additional expenses for vaccines that are approved and recommended for all children during the life of the contract.

Response: We agree with the commenter that children in separate child health programs should receive all recommended immunizations, as should children in Medicaid expansion and combination programs. Also, regardless of the type of child health insurance program the State chooses, we agree with the

suggestion that MCE contracts should provide that the MCEs furnish all vaccines, including new vaccines, recommended during the term of the contract.

However, regardless of whether the State chooses to include such a contract provision, States must furnish vaccines in accordance with the recommendations of the ACIP. States should furnish newly recommended vaccines to all eligible children within 90 days after the recommendation is published in *Morbidity and Mortality Weekly Report.* This report is available over the Internet at www.cdc.gov/mmwr.

We outlined ways that States could take advantage of the Federal discount contract price for vaccines in a letter dated June 25, 1999 to all State Health Officials. As stated in that letter, expenditures for vaccines will be matched by the Federal government at the enhanced SCHIP matching rate and will not count as expenditures subject to the 10 percent cap on administrative expenditures under section 2105(c)(2) of the Act, regardless of whether the State takes advantage of the Federal discount contracts.

Comment: Many commenters recommended that HCFA reconsider its position on the Vaccines For Children (VFC) program for various reasons. One commenter indicated that in light of national immunization goals not yet having been achieved, HCFA should not consider SCHIP enrolled children to be insured and

therefore ineligible for free VFC vaccines. Several commenters expressed that States that have elected to implement separate child health programs are being unfairly penalized for not choosing to expand their Medicaid programs.

One commenter indicated that because the SCHIP statute states absolutely that the legislation creates no entitlement, and because the VFC program defines insurance as benefits to which an individual is entitled, it would appear to be clear that, despite their eligibility for SCHIP, children in separate child health programs are not entitled to insurance and thus should be considered VFC-eligible. One commenter also stated that having seen polio epidemics and iron lung machines, HCFA should be working to reduce barriers that prevent many children from getting vaccinated so that epidemic childhood diseases do not become more prevalent in the United States as they are in other countries. One commenter believed that the interpretation of section 316 of the Public Health Service Act, which is used to support the policy that separate child health programs are not eligible to participate in VFC, is overly strict and does not align with the intent of the Act to insure that children receive necessary immunizations.

Response: We agree with the commenter that the intent of the statute is that all children should receive necessary immunizations, and therefore require at §457.410(b)(2) that all

States with separate child health programs provide coverage for immunizations in accordance with the recommendations of the ACIP. We disagree with the commenters only as to whether the VFC program or SCHIP funds cover the cost of required immunizations. We disagree that the VFC program allows payment for immunizations provided to a child enrolled in a separate child health plan. As explained in a letter to State Health Officials of May 11, 1998, section 1928(b)(2) of the Act defines a "Federally vaccine-eligible child" *or* a child who is entitled to free Federal vaccines under the VFC program, as "a Medicaid-eligible child, ...a child who is not insured, ...a child who is (1)administered a qualified pediatric vaccine by a Federally-qualified health center...or a rural health clinic...and (2) is not insured with respect to the vaccine, [or] a child who is an Indian...." The law further defines the term "insured" as a child "... enrolled under, and entitled to benefits under, a health insurance policy or plan, including a group health plan, a prepaid health plan, or an employee welfare benefit plan under the Employee Retirement Income Security Act of 1974...." The distinction between Medicaid coverage and other coverage is created by the VFC statute. Under the SCHIP statute, it is clear that children who are enrolled in a separate child health program must not be Medicaid-eligible, as explained in §457.310(b)(2) of these regulations. They are enrolled under,

and entitled to benefits under, a health insurance policy or plan within the definition in section 1928 (b)(2)(B)(ii), as explained above, and their insurance covers the cost of vaccines. Although there is no Federal entitlement to SCHIP coverage, a child who is enrolled in a SCHIP-funded plan is "entitled" to coverage under that plan just as a child enrolled under a group health plan is "entitled" to coverage under the group health plan. Unless they are Indians, children enrolled in SCHIP are not Federally vaccine-eligible under current law. Therefore, the Secretary cannot reconsider her decision on this matter without a change in the law that would define a child enrolled in a separate child health program as a Federally vaccine-eligible child.

Comment: One commenter indicated that it appears that the exclusion of SCHIP children from the VFC program would cause the SCHIP program to be less cost effective than the Medicaid program. The commenter asked if this policy means that States may use this provision as a cost offset in discussions of the revenue neutrality of the SCHIP program design. The Federal government, by design, assures that the SCHIP program will be more expensive in that it must pay for a service that is free under Medicaid.

Response: We do not understand the intent of this comment, as the concept of budget neutrality does not apply to the SCHIP program design. While immunizations are required to be covered

under a separate child health plan, States have discretion to determine what other services will be provided under their State plans, and the amount, scope, and duration of those services.

Comment: One commenter noted that it is crucial that any expansion of health care services in State plans include coverage for essential oral health care benefits. Historically, the number of dentists participating in State Medicaid programs is low. This low participation has prevented most poor children from developing good oral hygiene habits. SCHIP allows States to include oral health care services in their State plans and the commenter urged HCFA to consider this as an important component of increasing the overall health of America's rural children as the agency reviews State plans.

Response: We agree with the commenter that oral health is an integral part of the overall health of children and have engaged in a serious effort to promote oral health, as described earlier in a response to comments on this subpart. However, we do not have the statutory authority to require that States provide any specific services under their SCHIP plans other than those required under sections 2102(a)(7)(A) and 2103(c) of the Act. Although we do not have the authority to require the inclusion of these services, because of the importance of oral health services for children, we have included in the definition of well-baby and well-child care, for purposes of cost-sharing

restrictions at §457.520(b)(5), routine and preventive and diagnostic dental services. Accordingly, a separate child health plan may not impose copayments, deductibles, coinsurance or other cost-sharing for these services. Nonetheless, all but two States with separate child health programs have opted to provide coverage for some type of oral health services.

Comment: One commenter recommended that the regulation clarify that children enrolled under a Medicaid expansion program are entitled to all medically necessary services to the same extent as under the Medicaid EPSDT service and that the services for these children would not be considered a State option.

Response: The regulation indicates in §457.401(c) that the information in this subpart does not apply to Medicaid expansion programs. Therefore, because this subpart addresses only provisions regarding separate children's health insurance programs, we have not added additional language to the regulation text to indicate that children enrolled under Medicaid expansion programs are eligible for Medicaid's EPSDT services. However, as we have made clear in the preamble to the proposed regulation and in other guidance, all Medicaid benefit rules, including rules requiring EPSDT services, apply fully to children enrolled in Medicaid expansion programs.

Comment: One commenter noted that the Medicaid program includes coverage for children with serious and severe mental

illnesses. The commenter urged HCFA to collaborate with those States opting to develop separate child health programs to provide health coverage for the same level of treatment and service currently provided by Medicaid. Another commenter noted the importance of behavioral health as an integral part of a child's overall well being. According to this commenter, while rural families and children suffer mental disorders similar to those suffered by their urban counterparts, rural residents are less likely to receive treatment in part because of the extreme lack of behavioral health professionals in rural communities. The commenter strongly supported inclusion of coverage for mental health services in the State plans for the SCHIP program.

Response: We agree that mental health is an integral part of the overall health of a child and we urge States to consider providing these services. However, a requirement that States include any specific services in their State plans other than those required under 2102(a)(7)(A) and 2103(c) of the Act and specified under §457.410(b) would be inconsistent with title XXI.

Comment: One commenter asked why the discussion of §457.410(b) in the preamble to the proposed regulation about offering different health benefits coverage for children with special needs refers only to children with physical disabilities, and not mental disabilities. Such children may be encompassed within the category of special needs, but the additional listing

only of physical disabilities gives the false impression that disability cannot be mental as well.

Response: We did not intend to exclude any type of illness, physical or mental, by using the example of children with physical disabilities in discussing the States' option to offer different health benefits coverage. The preamble noted that States can have more than one benefit package that meets the requirements of the subpart, including one designed for children with special needs or physical disabilities. We were simply giving one example of a population to which States may want to consider offering additional services or a special package of services and did not mean to offer the example as the only option. States should consider the needs of children with mental disabilities as they consider whether to adopt benefit packages designed specifically for children with special needs.

Comment: One commenter supported the preamble language to proposed §457.410, which indicates that States can include in their comprehensive health benefits package "supplemental services for children with special needs or physical disabilities" and alternatively may offer multiple benefit packages. Such an approach permits States to expand services to children with special health care needs without regard to the 10 percent cap on Federally-matchable expenditures "for other than the comprehensive services packages." The commenter supported

this approach to increasing States' ability to help such children.

However, numerous commenters were concerned with this language in the preamble to proposed §457.410. Several commenters expressed concern about the language in the proposed rule stating that if a State offers a supplemental package of limited services for children with special health care needs that is not part of the comprehensive coverage required by the regulation, then expenditures for those extra services would be counted against the 10 percent cap on administrative expenses under section 2105(c)(2) of the Act. They noted that a number of States have implemented SCHIP with supplemental benefits packages, or "wrap-around packages", for coverage of services for eligible children with special health care needs and that this is an important, appropriate and beneficial strategy for the provision of needed health care services for children. They indicated that requiring that expenditures for services for children with special health care needs count against the 10 percent cap would encourage States to limit the services that are offered to these children, which could affect their overall health and well being. The commenters argued very strongly that services for children with special health care needs that are provided through an additional limited benefits package should not be counted against the 10 percent cap, and that making them

subject to the cap has the potential to discourage the development of creative benefit packages for children with special needs.

Two commenters questioned whether the Department intended to indicate that such initiatives are subject to the 10 percent administrative cap as section 2105(a)(2) makes no mention of special needs. The commenters recommended that the preamble be modified by dropping the reference to special needs since this reference may be misconstrued when States are designing and implementing certain benefit packages for special needs children. The commenters indicated that the statute contemplates that there are permissible health initiatives which would be subject to the 10 percent cap and suggested that this section of the preamble be written to identify the types of initiatives subject to the limitation without calling into question those benefits packages for children not subject to the 10 percent cap.

One commenter cautioned States about the manner in which they define children with special health care needs. The commenter provided suggested language that States should be encouraged to use to define children with special health care needs.

One commenter believed that the explanation of required coverage in the preamble to the proposed rule forces States either to provide a comprehensive benefit package that is above

and beyond the needs of the “average” child in order to ensure that the needs of special needs children are met, or to put administrative dollars at risk. By providing such a comprehensive benefit package, the capitated rate paid to health plans to pay for such services will significantly increase.

One commenter also noted that while the rules permit separate packages of services consistent with the ADA, the 10 percent cap is troubling and it is unclear what the potential impact will be or if this could penalize children and their families in unexpected ways.

Response: Unfortunately, the language in the preamble to the proposed rule about the application of the 10 percent administrative cap in connection with supplemental services for children with special needs caused much confusion to commenters. We will attempt to clarify below.

Under section 2105(a)(1), States may receive enhanced FMAP for expenditures for child health assistance for targeted low-income children provided in the form of health benefits coverage that meets the requirements of section 2103 of the Act. Under section 2105(a)(2) States may receive payment of a federal share of State expenditures for other items but expenditures for these other items are subject to the 10 percent administrative cap under section 2105(c)(2). A State has two options for providing more health benefits coverage to special needs children under

which the expenditures for the coverage are not subject to the 10 percent cap on administrative expenditures. The first option would be for the State to have a separate eligibility group for the identified special needs children with a larger health benefits package than for other eligibility groups. The State would have to design the eligibility group without violating the statutory requirement under section 2102(b)(1)(a) of the Act that the eligibility standards "not discriminate on the basis of diagnosis." The second option would be for the State to retain the general eligibility group that includes all children and include in the health benefits coverage package coverage for services needed by special needs children. The package could include limitations for coverage on these services (consistent with other benefits requirements) to ensure that they would be available primarily to special needs children. Under either option, the special needs coverage is part of an overall health benefits coverage package that is consistent with section 2103 of the Act and §457.410 of the final regulation.

One key aspect of section 2105(a)(2) is that SCHIP funds can be used for health services initiatives for targeted low-income children as well as other low-income children. With respect to the suggestion that we include some examples of public health initiatives that would be subject to the 10 percent cap, we are including the following examples, some of which were proposed by

one State: (1) access to mental health services for low-income children in the Juvenile Court System; (2) health care outreach and services for homeless children and adolescents; (3) mental health services for low-income children with special needs; (4) dental care for low-income children and their families; (5) health care services for migrant children; and (6) an immunization project for low-income children who are not enrolled in Medicaid or SCHIP. As we indicated, these are just a few examples for use of title XXI funds for public health initiatives as authorized by section 2105(a)(2) of the Act. States are free to develop and propose initiatives which are specific to the needs of their population.

Comment: One commenter noted that it was pleased that we have included a reference to Bright Futures in the proposed rule but encouraged that we use the term “well-adolescent” whenever we refer to “well-child” and the term “age” when offering examples of diverse populations.

Response: Under the definition of “child” set forth in section 2110(c)(1) of the Act, and implemented in §457.10 of this final regulation, “child” is an “individual under the age of 19.” An adolescent clearly fits within this definition of child, and therefore we have not accepted the commenter’s suggestion to use the term “well-adolescent” whenever we refer to well-child care. In addition, as we explained above, we did not intend to exclude

any particular group or condition in describing a special population that States may want to consider offering additional services or a special package of services. Therefore, we have not added “age” to the example we used in the preamble.

Comment: One commenter indicated that there are various ways for separate child health programs to make health benefits coverage available to enrolled children. States may use direct, fee-for-service coverage or can operate as primary care case managers. Separate child health programs can also buy benchmark or benchmark-equivalent coverage provided through an MCE. The commenter went on to say that what is listed as a class of covered benefits in the State plan may not be precisely what is covered if the State chooses to offer coverage solely through a benchmark or benchmark-equivalent package that is purchased from a participating insurer or MCE. Furthermore, the insurer or MCE may apply limits to coverage that would not apply if the coverage were obtained directly through the State-based plan. Finally, the proposed rules on coverage do not require any particular standard for the measurement of medical necessity for children, either by the State or by benchmark insurers.

According to the commenter, because the benchmark plans may differ from the State comprehensive package and no specific medical necessity standard is required for separate child health programs, the issue of disclosure of coverage and coverage

limitations becomes important. Both providers and families will need to have clear, understandable materials and information regarding what is and is not covered, as well as the limitations that apply to covered benefits. The commenter cautioned that benchmark plans may not be appropriately designed for children; for example, the plan may provide coverage for speech therapy after a stroke but no coverage for speech therapy to address developmental delays. There is nothing in the proposed rule that requires benchmark plans to be designed to meet the specific health needs of children.

Response: In order for a State plan to be approved, the State must indicate what type of health benefits coverage it is electing to provide. The State must make available to enrollees the full coverage package defined in its State plan, and may not permit contractors to restrict that coverage. While neither the State nor a contractor is required to furnish medically unnecessary services, they cannot alter the basic coverage package from that specified in the State plan.

Because SCHIP is targeted for children under the age of 19, States must ensure that the health benefits coverage it elects to provide is appropriate for the population being served. The statute addresses the issue of appropriateness of coverage through the coverage requirements at section 2103 of the Act, which sets forth the required scope of health insurance coverage

under a separate child health program. In addition, based on the authority of section 2102(a)(7) of the Act, we have required coverage for well-baby and well-child care, immunizations and emergency services. Finally, if a State elects to use benchmark-equivalent coverage, it must cover specific services listed at section 2103(c)(1) of the Act and be actuarially equivalent for additional services covered under one of the benchmark benefit packages. While we have not defined medical necessity for purposes of separate child health programs, we believe that the requirements of the statute and final regulations ensure the appropriateness of coverage for children in separate child health programs.

With respect to the commenter's concerns regarding the availability of understandable materials, we refer the commenter to the requirements at §457.110(b) and §457.525 which discuss the requirements for making certain information available and for information on the public schedule for cost sharing.

Comment: Several commenters agreed with HCFA's suggestion in the preamble to proposed §457.410 that SCHIP programs use the AAP guidelines and/or Bright Futures periodicity schedules. However, they did not agree with HCFA's reasoning for not requiring States to adopt this definition of well-baby and well-child for benefit coverage. One commenter indicated that Medicaid guarantees children coverage of medically necessary

services through EPSDT, while separate child health programs do not provide the same guarantee. It is therefore more critical and appropriate for HCFA to place specific requirements on the provision of services because there is no underlying entitlement, and HCFA should establish an appropriate floor. Another commenter indicated that because Medicaid uses the EPSDT standard for its schedule of periodicity, the schedule should be included for SCHIP coverage to be consistent and allow parity. Rather than merely recommending periodicity schedules, HCFA should require that an endorsed professional standard be adopted by SCHIP programs. Allowing States to devise their own schedules could leave children in different States with widely different coverage under SCHIP.

Response: For a number of reasons, we are not requiring States to use for coverage and other purposes the definition of well-baby and well-child care that is required for purposes of cost sharing. Specifically, HCFA wanted to assure States the flexibility accorded them under the statute in developing their SCHIP benefit packages, including their well-baby and well-child care packages. In addition, there are several expert groups that have developed professional standards for the delivery of well-baby and well-child care. These standards include those developed by the AAP, AAPD and the Bright Futures standards. HCFA has not endorsed any particular professional standard for

well-baby and well-child care for Medicaid and we did not feel we should impose a more stringent standard on SCHIP plans. We have included a definition of well-baby and well-child care for purposes of cost sharing because Congress established basic rules for cost sharing that must be applied on a consistent basis across States.

The commenter is correct that under the Medicaid program, EPSDT services are mandatory for most Medicaid eligible children under the age of 21. However, the SCHIP statute did not require this comprehensive service package for children in separate child health programs but rather gave States the flexibility to design their own benefit packages within certain parameters.

With respect to the use of a specific periodicity schedule, the commenter is incorrect that EPSDT services require any specific periodicity schedule. HCFA cannot, by law, require States to use any particular periodicity schedule for the delivery of EPSDT services under Medicaid. The EPSDT statute at section 1905(r) specifies that each State must develop its own periodicity schedule for screening, vision, hearing and dental services after appropriate consultations with medical and dental organizations involved in child health care. In the proposed rule, we suggested that States use one of the professional standards already developed in determining their well-baby and well-child care benefit packages; however, we have declined to

require the use of a specific schedule. There are several professional standards that are acceptable for States to adopt. In fact, many States have adopted one of those standards for use in their EPSDT programs also. This policy does present the possibility, as the commenter suggests, that children may be treated differently in different States. However, this is allowable under title XXI. Comment: One commenter believed that States should be able to retain discretion to define well-baby and well-child care more broadly than §457.520 and that HCFA should require States to follow the AAP and Bright Futures periodicity schedules in both Medicaid and SCHIP programs. In particular, many States have not yet adopted a periodicity schedule providing for annual health assessments for adolescents, even though there is consensus among the professional community that adolescents should receive annual assessments.

Response: If a State chooses to define well-baby and well-child care more broadly than defined in §457.520 for cost sharing purposes in order to limit cost sharing for a broader range of services, the State is free to do so. It is true that some States have not adopted periodicity schedules to allow for annual assessment of adolescents under their Medicaid program. While both programs allow for that flexibility in adopting periodicity schedules, HCFA encourages States to ensure that their periodicity schedules reflect current professional standards.

Comment: One commenter recommended that the AMA's Guidelines for Adolescent Preventive Services (GAPS) be added to the list of appropriate standards for States to consider.

Response: We agree that GAPS is an appropriate standard for States to use in defining well-child care periodicity schedules for adolescents and recommend that States consider this standard as well.

Comment: One commenter reiterated that the preamble language indicates that well-baby and well-child care includes health care for adolescents and is subject to the cost-sharing prohibitions, but is ambiguous as to whether a State has to provide coverage for these services or merely apply the cost-sharing prohibitions to those services that they cover. The commenter believed that States should be required to provide such coverage. The commenter also urged HCFA to add language to the preamble encouraging States to consider the special problems that affect adolescents (for example, eating disorders) when defining special needs.

Response: We appreciate the commenter's concern about adolescents. States are required to provide coverage for well-baby and well-child care services under any separate child health plan but may specifically define those services as they choose. We note that we have revised §457.410(b)(1) to provide that the State must obtain well-baby and well-child care services as

defined by the coverage for the State. Cost sharing is not allowed for any services covered under a separate child health program that are included in the definition of well-baby and well-child care at §457.520. We have not included language encouraging States to consider special problems that affect adolescents when defining special needs. However, we urge States to consider the special needs of the population being served by the separate child health plan.

Comment: One commenter recommended §475.410(b) be deleted because the statute provides States with the flexibility to adopt a benchmark plan or to develop an actuarially equivalent benefit package.

Response: We have not adopted this suggestion. The commenter correctly notes that the SCHIP statute provides States with flexibility to adopt benchmark health benefits coverage or actuarially equivalent benefit-equivalent health benefits coverage when designing their programs. However, in accordance with section 2102(a)(7), §457.410(b) ensures that enrollees in separate child health programs receive coverage for certain basic services.

4. Benchmark health benefits coverage (§457.420).

Section 2103(b) of the Act sets forth the benchmark health benefits coverage from which a State may choose in accordance with section 2103(a)(1) of the Act. We proposed to implement

these statutory provisions at §457.420. We proposed to define benchmark health benefits coverage as health benefits coverage that is substantially equal to the health benefits coverage in one of the following benefit packages:

- The Federal Employee Health Benefits Program (FEHBP) Blue Cross/Blue Shield Standard Option Service Benefit Plan with Preferred Provider arrangements;
- A health benefits plan that the State offers and makes generally available to its own employees; or
- A plan offered by a Health Maintenance Organization (HMO) that has the largest insured commercial, non-Medicaid enrollment of any such plan in the State.

We discussed each option for benchmark health benefits coverage in detail in the preamble of the proposed rule. We noted that when a State chooses to increase, decrease, or substitute coverage available under its approved State plan, a State must submit a State plan amendment for approval if the change in benefits is intended to conform the separate State benefit package to the benchmark coverage. But if the change in benefits causes the State offered benefits to differ from the benchmark coverage, then the benefits must be reclassified as benchmark equivalent or one of the other benefit package options.

We also noted that section 2103(a)(1) of the Act provides that benchmark coverage must be “equivalent” to the benefits

coverage in a reference benchmark benefit package. We stated that we would interpret this language to mean that coverage must be "substantially equal" to benchmark coverage. That is, benchmark coverage offered under a separate child health plan should differ from benchmark coverage available in the State only to the extent that the State must add coverage to the benchmark coverage, such as coverage for immunizations, to meet the requirements of title XXI.

Comment: Numerous commenters had requested clarification of when a State plan amendment is required if a benchmark plan changes. These commenters interpreted the language at §457.20 of the proposed rule to mean that if the benchmark plan the State is using changes, we would not require a State plan amendment; whereas if the State chooses to change the coverage under its State plan to conform to the benchmark plan's changes, a plan amendment would be required. The commenters asked why changes to a State plan that simply parallel changes in a benchmark plan require an amendment given that benchmark plans are supposed to be the standard of adequacy in terms of SCHIP benefits.

Several commenters believed the preamble should be clarified to indicate that an amendment is only required when the SCHIP benefits package is altered.

Response: The approved State plan must accurately reflect the health benefits package being offered. A State must submit a

State plan amendment to reflect any change in the health benefits coverage regardless of whether the change is made to conform to changes made in the benchmark plan to which the State's health benefits coverage is supposed to be equivalent, or whether the change is made to select a different health benefits coverage option. See subpart A for further discussion of when a State must submit a State plan amendment.

Comment: One commenter felt that States should not be allowed to amend their State plans to make them less comprehensive in terms of coverage or the benefits they provide. According to this commenter, State plans should only be amended to improve coverage, not to diminish it. A basic package of benefits should be required. In other words, certain benefits should be Federal entitlements. States then have the flexibility to improve that benefit package or to offer only what is Federally required.

Response: States are responsible for determining the health benefits coverage under a separate child health program subject to the standards set by title XXI and implemented in this final regulation. States have the option of choosing from the types of coverage specified in §457.410 of the proposed rule and in accordance with section 2103 of the Act. States may amend their State plans to decrease the coverage provided as long as all of the requirements of §§457.410 - 457.490 are met, depending on the

type of coverage approved in the State plan. The only services required to be covered under every separate child health program are well-baby and well-child care, immunizations according the ACIP schedule, and emergency services as defined in §457.10.

Comment: One commenter was concerned that a State that is using the benchmark benefit package need not submit an amendment when the benchmark changes and believed this means that if the plan includes mental health services that are subsequently dropped, the State need not file a State plan amendment.

Response: If a State has elected to provide benchmark health benefits coverage that is substantially equal to coverage under a certain benefit plan, and that plan drops coverage for mental health services, the State has two options. First, the State may continue to provide coverage for mental health services as described in its approved State plan, even though the benchmark plan has discontinued this coverage. No amendment is necessary in this case. Alternatively, if the State wants to discontinue providing mental health services under its State plan, it must submit a State plan amendment to reflect the dropped coverage.

Comment: One commenter supported the preamble language on benchmark coverage being able to differ from coverage under a benchmark plan only as necessary to meet other requirements of title XXI.

Response: We appreciate the support. The commenter is correct that benchmark health benefits coverage under §457.420 may only differ from coverage under the benchmark plan as necessary to meet title XXI requirements. For example, as noted earlier, a State may need to add coverage for immunizations in order to comply with the requirement that they be covered under every separate child health plan.

Comment: One commenter stated that the preamble indicates in discussing §457.420(c) that "in calculating commercial enrollment, neither Medicaid nor public agency enrollees will be counted." The commenter suggested that all public agency enrollees be counted as commercial enrollees when they are enrolled in a plan offered by a private sector HMO. If it is appropriate to count Federal employees as commercial enrollees, it should be just as appropriate to count any other public employees who are enrolled in the plan. Another commenter recommended that §457.420(c) be modified to be consistent with the preamble to exclude public agency enrollees. The proposed regulation only excludes Medicaid enrollees.

Response: We agree with the comments noting that the preamble and regulation text were not consistent with respect to the calculation of commercial enrollment. We also recognize, as noted by one of the commenters, that the preamble statement that Federal employees are considered commercial enrollees, but public

agency enrollees are not, merits further consideration.

After further consideration, we have decided to retain the regulatory language as proposed, that is, the health insurance coverage plan that is offered through an HMO and has the largest insured commercial, non-Medicaid enrollment in the State. Public agency employees, as well as Federal employees, may be considered enrollees for purposes of calculating commercial enrollment.

5. Benchmark-equivalent health benefits coverage (§457.430).

Section 2103(a)(2) of the Act provides that a State may opt to provide a benefits package with an aggregate actuarial value that is at least equal to the value of one of the benchmark benefit packages. In accordance with the statute, we proposed at §457.430 that the benchmark-equivalent coverage must have an aggregate actuarial value, determined in accordance with proposed §457.431, that is at least actuarially equivalent to coverage under one of the benchmark packages outlined in §457.420.

In §457.430 we set forth the proposed coverage requirements for States selecting the benchmark-equivalent coverage option. Under the authority of section 2103(c)(1), we proposed that a benchmark equivalent plan must include coverage for inpatient and outpatient hospital services, physicians' surgical and medical services, laboratory and x-ray services, well-baby and well-child care, including age-appropriate immunizations provided in accordance with the recommendations of ACIP.

Under the authority of section 2110(a) of the Act as implemented at proposed §457.402, a State may provide coverage for a wide range of services. Under the authority of section 2103(a)(2)(C), we proposed that if the State provides coverage for prescription drugs, mental health services, vision services, or hearing services, the coverage for these services must have an actuarial value that is equal to at least 75 percent of the actuarial value of the coverage of that category of service in the benchmark benefit package. In addition, we proposed that if the benchmark plan does not cover one of the above additional categories of services, then the benchmark-equivalent coverage package may, but is not required to, include coverage for that category of service. A State may provide services listed in §457.402 other than the services listed in §457.430(b) without meeting the 75 percent actuarial value test.

Comment: Two commenters believed §457.430 is ambiguous, confusing and potentially troublesome and allows for a court to read some distinction into the redundant provisions at 457.410(b)(1) and (2) and 457.430(b)(4) about well-baby and well-child care and immunizations applying only to benchmark-equivalent coverage. To avoid such a result, the commenter suggested that HCFA strike §457.430(b)(4) and revise subsection (b) to read as follows: "(b) Required services. Benchmark equivalent health benefits coverage must include, in addition to

the services described in §457.410(b), coverage for the following categories of service."

Response: We have accepted the commenter's suggestion to revise proposed §457.430. We have also revised §457.410((b)(2) of the regulation text to add the phrase "age appropriate" to immunizations in order to make it consistent with proposed §457.430(b)(4).

Comment: One commenter is concerned because mental health services do not fall within the scope of *required* services under SCHIP. The commenter is particularly concerned that children in a State that initially use a Medicaid-expansion program and then move to a separate child health program will lose the EPSDT safety net for mental health services.

Response: While children receiving SCHIP services under a Medicaid-expansion program are required to be provided the full complement of EPSDT services, there is no such requirement under a separate child health program. It is true that some children with coverage for mental health services under a Medicaid expansion could lose that coverage if the State decided to switch to a separate child health program. Those children, however, would be in no worse position than if the State had originally elected a separate child health program. We have no basis to limit State flexibility by mandating benefits beyond those specifically required by the statute, however, we encourage

States electing to shift from a Medicaid expansion program to a separate child health program or combination program to retain a comprehensive benefits package that is similar to the Medicaid expansion benefit package to help ensure that children do not experience a significant disruption in care.

Comment: One commenter believed HCFA should promulgate minimum benefits standards for benchmark-equivalent coverage. They noted that HCFA indicated that it has chosen not to propose minimum standards for basic sets of services because a greatly reduced benefits schedule would be unlikely to meet actuarial value requirements. However, the commenter argues that because SCHIP plans may involve much lower cost-sharing requirements than commercial plans, a SCHIP benefits package can offer far fewer services than a benchmark commercial plan and still pass actuarial muster. Accordingly, the commenter respectfully urged the Secretary to revisit this decision and promulgate minimum benefits standards for benchmark-equivalent coverage.

Response: We have considered the issue raised by the commenter but have declined to revise the regulation to set minimum standards at this time. The actuarial value requirements should ensure that the benefits in an actuarial-equivalent benefit package that will not fall below levels intended by title XXI. In fact, experience has shown that States that have chosen to provide benchmark-equivalent health benefits coverage provide

coverage that looks very similar to coverage under other health benefits coverage options.

Comment: One commenter recommended deleting §457.430(c)(2) because benchmark-equivalent coverage should not be required to include coverage for specific services just because they are covered in the benchmark package. According to this commenter, the intent of equivalent packages is to allow a State the flexibility to design coverage that meets the needs of children in the state.

Response: The language in §457.430(c)(2) mirrors section 2103(a)(2)(C) of the Act. Therefore, we have not adopted the commenter's suggestion to delete this material.

6. Actuarial report for benchmark-equivalent coverage (§457.431).

In accordance with section 2103(c)(4) of the Act, at §457.431 we proposed to require a State, as a condition of approval of benchmark-equivalent coverage, to provide an actuarial report, with an actuarial opinion that the benchmark-equivalent coverage meets the actuarial requirements of §457.430. We also proposed that the actuarial report must specify the benchmark coverage used for comparison.

The actuarial opinion must meet all the provisions of the statute. We proposed that the report must explicitly state the following information:

• The actuary issuing the opinion is a member of the American Academy of Actuaries (and meets Academy standards for issuing such an opinion).

• The actuary used generally accepted actuarial principles and methodologies of the American Academy of Actuaries, standard utilization and price factors, and a standardized population representative of privately insured children of the age of those expected to be covered under the State plan.

• The same principles and factors were used in analyzing both the proposed benchmark-equivalent coverage and the benchmark coverage, without taking into account differences in coverage based on the method of delivery or means of cost control or utilization used.

• The report should also state if the analysis took into account the State's ability to reduce benefits because of the increase in actuarial value due to limitations on cost sharing in SCHIP.

Finally, we proposed that the State must provide sufficient detail to explain the basis of the methodologies used to estimate the actuarial value or, if requested by HCFA, to replicate the State's result.

Comment: We received two comments on this section. One commenter supported the requirement for a set of comprehensive actuarial reports. The second commenter suggested that the

requirement for proof of actuarial equivalence of the benefits will be too costly. The commenter noted that insurance industry and State regulatory departments have developed methods of comparing coverage that would be significantly more cost effective and equally as useful for the program as an actuarial study.

Response: We appreciate the support of the first commenter. In response to the suggestion of the second commenter, the actuarial report requirements contained in this section of the regulation text are basically drawn from the section 2103(c)(4) of the Act. Therefore, we have chosen not to alter the requirements in the regulation to allow an alternative approach to benchmark equivalent coverage. However, as discussed under §457.450, we are willing to entertain other suggestions for Secretary-approved coverage. We will consider States' specific proposals for alternatives to actuarial analysis under the provisions of §457.450.

7. Existing comprehensive State-based coverage (§457.440).

In accordance with section 2103(d) of the Act, at §457.440 we proposed that existing comprehensive State-based health benefits coverage must include coverage of a range of benefits, be administered or overseen by the State and receive funds from the State, be offered in the State of New York, Florida, or Pennsylvania, and have been offered as of August 5, 1997. In

essence, Congress deemed the existing State-based health benefit packages of three States as meeting the requirements of section 2103 of the Act. We noted that these States still need to meet other requirements of title XXI, including requirements relating to cost sharing, such as copayments, deductibles and premiums, as specified in subpart E of this final rule.

We also proposed that the States (Florida, New York, and Pennsylvania) may modify their existing, comprehensive, State-based program under certain conditions. First, the program must continue to offer a range of benefits. Second, the modification must not reduce the actuarial value of the coverage available under the program below either the actuarial value of the coverage as of August 5, 1997 or the actuarial value of a benchmark benefit package. A State must submit an actuarial report when it amends its existing State-based coverage.

We did not receive any comments on this section. Therefore, we are implementing these provisions as set forth in the proposed rule except that we have added language to the regulation to clarify that a State must submit an actuarial report when it amends its existing State-based coverage.

8. Secretary-approved coverage (§457.450).

Section 2103(a)(4) of the Act defines Secretary-approved coverage as any other health benefits coverage that provides appropriate coverage for the population of targeted low-income

children to be covered by the program. In proposed §457.450 we set forth the option of providing health benefits coverage under the Secretary-approved health benefits coverage option.

We proposed that the following coverage be recognized as Secretary-approved coverage under a separate child health program:

• Coverage that is the same as the coverage provided under a State's Medicaid benefit package as described in the existing Medicaid State plan.

• Comprehensive coverage offered under a §1115 waiver that either includes coverage for the full EPSDT benefit or that the State has extended to the entire Medicaid population in the State.

• Coverage that includes benchmark coverage, as specified in §457.420, plus additional coverage. Under this option, the State must clearly demonstrate that it provides all the benchmark coverage, including all coverage required under title XXI, but may also provide additional services.

• Coverage, including coverage under a group health plan, purchased by the State that the State demonstrates to be substantially equal to coverage under one of the benchmark plans specified in §457.420, through use of a benefit-by-benefit comparison of the coverage. Under this option, if coverage for just one benefit does not meet or exceed the coverage for that

benefit under the benchmark, the State must provide an actuarial analysis as described in §457.431 to determine actuarial equivalence.

While we listed these four options as permissible types of Secretarial-approved coverage, we solicited comments on other specific examples of coverage packages that States have developed, or might wish to develop, to meet the Title XXI requirements. We also proposed that no actuarial analysis is required for Secretary-approved coverage if the State can show that the proposed benefit package meets or exceeds the benchmark coverage. While the four options we listed meet or exceed the benchmark package, it is possible that a State may develop a Secretary-approved coverage proposal that may require an actuarial analysis.

Comment: One commenter argued that "Secretary-approved coverage" should provide HCFA with greater flexibility to approve SCHIP State plans. The commenter points out that Secretary-approved coverage is not simply another name for benchmark coverage; title XXI provides for Secretary-approved coverage as a flexible way for HCFA to approve a State plan. The statute requires no actuarial analysis for this option but rather requires only that the coverage be deemed "appropriate" for the target population.

The commenter recommended that the regulations should simply

indicate that States must demonstrate, to the Secretary's satisfaction, that their coverage meets the needs of their SCHIP populations. The manner in which States make this demonstration should be left flexible in accordance with the discretion accorded to States by title XXI.

Response: The list of four examples included in the regulation text at §457.450 was not meant to be an exhaustive list of examples of Secretary-approved coverage. The regulations text states that Secretary-approved coverage "may include" one of these options. We solicited additional examples of types of coverage that might qualify under this option but we did not receive any specific examples. We remain open to reviewing other proposals for Secretary-approved coverage.

Comment: One commenter noted that a number of States are exploring buy-in programs where SCHIP funds will be used to subsidize coverage for the uninsured under group health plans. A significant issue for States is how to design programs that can meet HCFA's SCHIP benefit requirements. The preamble to the proposed rule states that if any benefit under an employer plan does not meet or exceed that of a benchmark plan provided under title XXI, based on a benefit-to-benefit comparison, the State must document that the two benefit packages are actuarially equivalent. However, providing such comparisons would likely be costly and burdensome to implement on an employer-by-employer

basis. The commenter strongly encouraged HCFA to modify the preamble to provide for maximum State flexibility in the area of benefit certification under buy-in programs. HCFA could provide such flexibility by allowing States more flexibility to designate benefit packages that meet the benchmark standard or to use simple benefit checklists.

Response: We recognize the administrative burden involved in determining whether employer plans meet benefit requirements for separate child health programs, and we agree that documenting the actuarial equivalence of a plan or using benefit side-by-side comparisons may be costly and burdensome. Nonetheless, employer plans through which States wish to offer coverage under a separate child health program must meet requirements for either benchmark coverage, benchmark-equivalent coverage, or Secretary-approved coverage in order to comply with section 2103 of the Act. However, we are open to, and encourage States to propose other options under the "Secretary-approved" category.

Comment: Two commenters recommended that proposed §457.450 should explicitly reference Medicaid benefits for children rather than permit States to furnish SCHIP children with Medicaid benefits for adults without any actuarial analysis showing comparability to standard commercial benefits. Specifically, paragraphs (a) and (b) should be consolidated and revised to read: "(a) Coverage that is the same as the coverage for children

provided under the Medicaid State plan."

Response: While we have not adopted the exact language and consolidation recommended by the commenter, we have revised §457.450(a) to specify that coverage should be the same as that offered to children under the Medicaid State plan.

Comment: One commenter believed the proposed rule should be amended to eliminate the use of a benefit-by-benefit comparison for determining whether coverage provided through premium assistance under a group health plan is approvable. This provision appears to require benefit-by-benefit comparison for demonstrating that group health plans meet or exceed coverage requirements. This is a more rigorous test than that required for benchmark equivalent coverage purchased directly by States. Premium assisted group health plan coverage should be held to no more than the requirements for benchmark equivalent coverage.

The commenter noted that their State experience has shown that children are more likely to be insured if their parents are insured and that parents prefer to cover their entire family under the same plan. HCFA's imposition of barriers to the use of SCHIP programs to support group health coverage is a misguided attempt to address substitution of coverage. States should be given as much flexibility as possible to test different approaches, including buy-in to employer sponsored plans, for increasing creditable coverage for uninsured children. HCFA

should not add any restrictions to those already established by law in title XXI.

Response: We did not intend to impose additional restrictions on States wishing to utilize premium assistance programs in SCHIP. The benefit-by-benefit comparison was developed in response to States who wanted to provide premium assistance through employer sponsored insurance but were concerned about the cost of performing the actuarial analysis required by the statute for each participating employer plan. Therefore, we proposed that States may compare each benefit to the benefits in the benchmark plan as a way of providing States with a simplified and lower cost option to the actuarial analysis. However, given the statutory requirement for actuarial equivalence we still require that States perform an actuarial analysis if one benefit is lower than the level specified in the benchmark plan.

9. Prohibited coverage (§457.470).

In accordance with section 2103(c)(5) of the Act, we proposed at §457.470 that a State is not required to provide health benefits coverage under the plan for an item or service for which payment is prohibited under title XXI even if any benchmark package includes coverage for that item or service. We did not receive any comments on this section. Therefore, we are implementing these provisions as set forth in the proposed rule.

10. Limitations on coverage: Abortions (§457.475).

This section implements sections 2105(c)(1) and (c)(7) of the Act, which set limitations on payment for abortion services under SCHIP. At §457.475, we proposed that FFP is not available in expenditures for an abortion, or in expenditures for the purchase of health benefits coverage that includes coverage of abortion services, unless the abortion is necessary to save the life of the mother or the abortion is performed to terminate a pregnancy resulting from an act of rape or incest.

Additionally, we proposed that FFP is not available to a State in expenditures of any amount under its title XXI plan to assist in the purchase, in whole or in part, of health benefits coverage that includes coverage of abortions other than to save the life of the mother or resulting from an act of rape or incest.

We also proposed that, if a State wishes to have managed care entities provide abortions in addition to those specified above, those abortions must be provided pursuant to a separate contract using non-Federal funds. A State may not set aside a portion of the capitated rate to be paid with State-only funds, or append riders, attachments, or addenda to existing contracts to separate the additional abortion services from the other services covered by the contract. The proposed regulation also specified that this requirement should not be construed as

restricting the ability of any managed care provider to offer abortion coverage or the ability of a State or locality to contract separately with a managed care provider for additional abortion coverage using State or local funds.

Comment: One commenter recommended that abortions be covered under any circumstances.

Response: Federal financial participation is available in expenditures for abortions in an SCHIP program only as specifically authorized by Congress in the statute. Section 2105(c)(1) of the Act limits funding of abortions to funding for those abortions necessary to save the life of the mother or to terminate pregnancies resulting from rape or incest.

Comment: We received many comments on the requirement that States that wish to cover abortions other than those allowed under the statute use separate contracts with managed care organizations to ensure that no Federal SCHIP funds are used to pay for those additional abortions. The commenters believed that this requirement exceeds the statutory authority, will be burdensome for States and managed care entities, and may ultimately serve to dissuade States and managed care entities from offering abortion services. Several commenters also indicated that enforcement of the requirement is not feasible in an employer-sponsored insurance environment where the benefits package is predetermined by an employer and a commercial insurer,

rather than by the State. They recommended that employer-sponsored programs be exempt from the separate contract requirement.

Response: Section 2105(c)(7) of the Act specifies that "payment shall not be made to a State under this section for any amount expended under the State plan to pay for any abortion or to assist in the purchase, in whole or in part, of health benefit coverage that included coverage of abortion." Congressional authorities have made clear that this section of the statute requires separate contracts where managed care organizations will be providing abortions in addition to those specified in the law. Thus, contrary to the opinion of the commenters, this prohibition can not be satisfied by carving out or allocating a portion of the capitated rate to be paid for with State-only funds.

11. Preexisting condition exclusions and relation to other laws (§457.480).

In proposed §457.480 we implemented the provisions of sections 2103(f), and 2109 of the Act under the authority of section 2110(c)(6) we implemented the provisions of sections 2103(f), 2109 and 2110(c)(6). At §457.480(a), we proposed to implement section 2103(f) of the Act and provide that, subject to the exceptions in paragraph §457.480(a)(2), a State child health plan may not permit the imposition of any preexisting condition exclusion for covered benefits under the plan. In

§457.480(a)(2), we proposed that if the State child health plan provides for benefits through payment for, or a contract with, a group health plan or group health insurance coverage, the plan may permit the imposition of a preexisting condition exclusion but only insofar as permitted under ERISA and HIPAA.

In proposed §457.480(b), we implemented sections 2109 and 2103(f)(2) of the Act, which describe the relationship between title XXI and certain other provisions of law. Specifically, as set forth in proposed §457.480(b), these provisions include section 514 of ERISA, HIPAA, the Mental Health Parity Act of 1996 (MHPA) (regarding parity in the application of annual and lifetime dollar limits to mental health benefits) and the Newborns and Mothers Health Protection Act of 1996 (NMHPA) (regarding requirements for minimum hospital stays for mothers and newborns). See regulations at 45 CFR 146.136 for a discussion of the MHPA and 45 CFR 146.130 and 148.170 for a discussion of the NMHPA.

Comment: One commenter agreed with the inclusion of language in §457.480 requiring compliance with the Mental Health Parity Act. However, several commenters raised concerns because they interpreted the language at §457.480(b)(3) and (4) to mean that States must comply with the MHPA and the NMHPA, regardless of whether or not the State's benchmark plan includes these components. The commenters believed this requirement negates the

flexibility otherwise provided the State in choosing the option of using a separate child health plan. The commenters believed that this language should be removed from the final regulation and that States should decide if inclusion of these components in their separate child health programs is appropriate.

One commenter indicated that this requirement would require the offeror of the benchmark plan either to price a SCHIP product separately to the State, to incorporate the mental health parity costs and benefits, or to include these benefits at the same cost (an unlikely scenario). Either way, the commenter argued that the provision reduces the flexibility of using a benchmark plan and thus the proposed linkage of SCHIP to these laws is not appropriate and should be removed.

Response: We agree that the proposed regulation language was unclear and have revised the language to clarify this issue. The commenters appear to have interpreted the proposed rule to mean that States must provide coverage for mental health services and services for newborns and mothers regardless of whether a State's benchmark plan includes coverage for those services. We did not intend to impose such coverage requirements.

The requirements of the MHPA apply only to group health plans (or health insurance coverage offered by issuers in connection with a group health plan) that provide such medical/surgical benefits for newborns and mothers and mental

health benefits. Thus, the provisions of MHPA apply only to title XXI coverage provided through a group health plan and only if that plan offers mental health benefits. However, if a State uses a group health plan as a benchmark, then the State may be implicitly required to comply with the MHPA even if that law is not directly applicable. Similarly, the NMHPA applies directly only to group health plans and health insurance issuers (in the group and individual markets) providing benefits for hospital lengths of stay in connection with child birth. We did not intend to impose additional coverage requirements on States or to reduce the State's flexibility in defining its service packages. We have thus revised the regulations to clarify that only group health plans through which States provide coverage under a State plan are subject to the requirements of the provisions described in §§457.480(b)(3) and (4).

Comment: One commenter raised the issue of HIPAA requirements and the pre-existing condition exclusions. The commenter noted that because SCHIP enrollees generally will not meet the requirements of "eligible individuals" under HIPAA, the level of protection afforded by this proposed rule against pre-existing condition exclusion clauses in a SCHIP benchmark package offered by a private insurer is unclear. The proposed rule does state that SCHIP benefits are creditable coverage; however, the commenter stated that the prohibition against pre-existing

condition exclusions is triggered only if creditable coverage was followed by COBRA coverage. The commenter noted that clarification of the pre-existing condition exclusion provisions will be important for health providers caring for children with disabilities.

One commenter also indicated that the regulations do not permit any “preexisting conditions exclusions” for a State plan in general. However, if a SCHIP plan provides coverage through a group health plan, the plan could impose preexisting conditions exclusions in accordance with what is allowable under HIPAA. While HIPAA does limit the extent of preexisting condition exclusions, States should be allowed to negotiate with health plans the elimination of all preexisting condition exclusions.

Another commenter encouraged the inclusion of a statement at §457.480(a)(2) that while States may, in very limited circumstances, permit the imposition of a pre-existing condition exclusion consistent with applicable Federal law, States have the discretion to, and are encouraged to, negotiate group health plan coverage free of such exclusions.

Response: Section 457.480(a) of the regulation implements section 2103(f)(1) of the Act and provides that a State may not permit the imposition of a pre-existing condition exclusion, except in the case of a State that obtains health benefits coverage through payment for, or a contract with, a group health

plan or group health insurance coverage, in which case the State may permit the imposition of such an exclusion to the extent permitted under HIPAA. The protection afforded to enrollees is clear; they either face no pre-existing condition exclusion or, if enrolled in a group health plan, they potentially face an exclusion that in no case can be longer than the 12 months permitted under HIPAA. The commenter correctly notes that enrollees in a separate child health program may not meet the definition of "Federally eligible individual" under HIPAA's individual market protections (although they may if their most recent coverage was SCHIP coverage through a group health plan and they then exhausted any COBRA or State continuation coverage offered to them). Presumably, the commenter was concerned about former enrollees wishing to purchase private, individual market coverage. Title XXI does not provide enrollees with an assurance of meeting the definition of Federally-eligible individuals under HIPAA. However, section 2110(c)(2) of the Act as implemented at §457.410 provides that coverage meeting the requirements of §457.10 provided to a targeted low-income child constitutes creditable health coverage. Therefore, coverage under a separate child health program will count towards the minimum 18 months of coverage required for someone to qualify as a Federally-eligible individual.

Comment: One commenter also urged States that do and do not

have mental health parity statutes to include coverage for a full range of mental illness services in their State plans when they opt to develop separate child health programs.

Response: States are given flexibility in designing their benefit packages. While we encourage States to provide services for mental illness, there is no Federal requirement for a State to include this coverage under its separate child health program if it does not elect to do so.

Comment: One commenter believed the regulation should include a statement that pre-existing condition exclusions are contrary to the intent of SCHIP and unfair. Therefore, even under the limited circumstances where such exclusions are allowed, States must be required to demonstrate attempts to negotiate group health plan coverage free of such exclusions. According to this commenter, only after demonstrating that those efforts have been exhausted, should a State plan with these very limited exclusions be approved.

One commenter asserted that the HIPAA-allowable conditions for permitting a waiting period for services for a preexisting condition are adverse to the purposes of initiating coverage for children cut off from access to services precisely because they lack coverage. The commenter believed most, if not all, children should be assessed, diagnosed, and treated quickly in response to their health deficiencies. The commenter believed this is a

matter for Congress to reconsider.

Response: The language in the proposed rule at §457.480(a)(1) and (2) was included based on section 2103(f)(1) of the Act. Section 2103(f)(1)(B) clearly provides for the possibility that States providing benefits through group health plans may allow those plans to impose pre-existing condition exclusions to the extent permitted by HIPAA. One limited exception to this rule is permitted. Under §2103(f)(1)(B) of Title XXI, if a State child health plan provides for benefits through payment for, or a contract with, a group health plan or group health insurance, the plan may permit the imposition of those preexisting conditions which are permitted under HIPAA. This permits the imposition of preexisting conditions consistent with the requirements of such plans when the State is providing premium assistance through SCHIP to subsidize child or family coverage under a group health plan or group health insurance pursuant to §2105(c)(3) of the statute. Therefore, we are unable to revise this section as suggested by the commenter.

12. Delivery and utilization control systems (§457.490).

In accordance with section 2102(a)(4) of the Act, at §457.490 we proposed to require that State plans include a description of the type of child health assistance to be provided including the proposed methods of delivery and proposed utilization control systems. In describing the methods of

delivery of the child health assistance using title XXI funds, the proposed regulation requires a State to address its choice of financing and the methods for assuring delivery of the insurance product to children including any variations. We also proposed that the State describe utilization control systems designed to ensure that children use only appropriate and medically necessary health care approved by the State or its subcontractor. We set forth examples of utilization control systems in the preamble to the proposed rule.

Comment: One commenter noted that in this section of the proposed rule, HCFA requests a description of utilization controls designed to ensure that children use only appropriate and medically necessary health care, but does not define "medically necessary" in any specific manner. The commenter suggested that this term be defined in the regulation and suggested language to be used in the regulation as a definition of medically necessary.

Response: As we have indicated in response to comments on §457.420, HCFA will not define medical necessity for SCHIP. The determination of medical necessity criteria for separate child health programs is left up to each State to define.

Comment: One commenter noted that utilization controls that might be appropriate for the adult population may not be appropriate for the pediatric population. As States implement

these controls, it is important that they are appropriate for children. These controls should take into consideration children with special health care needs as well as the unique needs of children in general.

Response: The language in §457.490(a) of the proposed rule very specifically says "methods for assuring delivery of insurance products to the children." Section 457.490(b) provides for "systems designed to ensure that children use only appropriate . . ." (emphasis added). We believe this language, along with the language at proposed §457.735 (now §457.495) requiring States to assure appropriateness of care, very clearly requires that the utilization controls be appropriate for the pediatric population. If a State provides coverage for services for children with special health care needs, States would be expected to ensure appropriate utilization controls on these services also. We believe the language in paragraph §457.490(a) requiring States to describe methods to assure delivery of services "including any variations," is sufficient to address this commenter's concerns. "Variations" would include additional services delivered to special needs children.

Comment: We received two comments suggesting the addition of default enrollment language in the regulation. One commenter recommended that HCFA adopt language similar to the language in the Medicaid managed care proposed rule to address default

enrollment under SCHIP for States that offer eligible children a choice of plans. The commenter suggested that HCFA require that States describe in their plans the policies and procedures that they will use to minimize rates of default enrollment and what efforts the State and its contractors will make to preserve traditional provider-patient relationships. The commenter also recommended that this section include an additional paragraph:

> Describe policies and procedures that minimize rates of default enrollment where beneficiaries have a choice of plans, and what efforts have been made by the State and its contractors to preserve existing provider/patient relationships. States must also describe opportunities for beneficiaries to disenroll both for cause or on a periodic basis without cause.

Response: Default enrollment, also referred to as auto assignment, is a practice utilized by several States in their enrollment processes. However, we believe that any information or requirements regarding managed care enrollment procedures, including default enrollment, should be addressed as part of the requirements of §457.110(a), rather than in this section.

Comment: One commenter supported the language in this section and indicated that this sets out a helpful framework that encourages States to ensure that utilization controls limit costs without denying essential health care to children. Response:

We appreciate the commenter's support.

Comment: One commenter recommended that §457.490(a) be modified to be applicable not only to the delivery of the insurance products but also to delivery of services covered by the product.

Response: We have adopted this suggestion and revised the regulation text accordingly.

Comment: Two commenters recommended that this section be modified to require State plans to identify methods the States will use to monitor and evaluate delivery and utilization control systems to ensure that children receive appropriate and medically necessary care.

Response: Proposed §457.735 (now §457.495) addresses State plan requirements for assuring quality and appropriateness of care provided under the plan. Please see our responses to comments in that section.

13. Grievances and appeals (proposed §457.495).

At §457.495, we proposed to require States to provide enrollees in a separate child health program with the right to file grievances or appeals for reduction or denial of services in accordance with proposed §457.985. In an effort to consolidate all provisions related to review processes, we have removed proposed §457.495 and incorporated those provisions into new subpart K, which contains provisions regarding grievances and

appeals. We address comments on proposed §457.495 in new subpart K.

14. State plan requirement: State assurance of the quality and appropriateness of care (**§**457.495).

Sections 2102(a)(7)(A) and (B) of the Act require the State plan to describe the strategy the State has adopted for assuring the quality and appropriateness of care, particularly with respect to providing well-baby care, well-child care and immunizations, and for ensuring access to covered services, including emergency services. We proposed to implement this provision at **§**457.735(a), and provided further specifications therein consistent with this statutory requirement.

We also proposed to include additional, more specific assurances designed to ensure the quality and appropriateness of care for particularly vulnerable enrollees. In **§**457.735(b), we proposed that States must provide assurances of appropriate and timely procedures to monitor and treat enrollees with complex and serious medical conditions, including access to specialists.

In this final rule, we are redesignating the provisions of proposed §457.735 (which were previously located in subpart G, Strategic planning) as §457.495. We believed that these provisions are more appropriately presented in the context of this subpart. We respond to all public comments on proposed §457.735 below.

Comment: We received several comments indicating that this section of the proposed rule was unclear as to whether the requirement for State assurance of quality and appropriateness of care applies to SCHIP coverage provided through employer plans. Commenters indicated that the requirements of the proposed regulation seem tacitly to assume that the State will have a direct, contractual relationship with all SCHIP participating health plans, including employer-sponsored plans. A commenter further stated that any attempt to apply such requirements directly to employer-sponsored plans would mean that no employer plans will ever qualify for the State's premium assistance under SCHIP, as there is no incentive for an employer or plan to invest resources to comply with these requirements. Commenters indicated that employer-sponsored health coverage systems do not identify individuals who can be classified into such categories as "enrollees with special or complex medical conditions," making it difficult to report on these subgroups.

Response: We understand the commenters' concerns and desire that data reporting requirements under SCHIP are able to work within the systems and regulatory structure for premium assistance programs. The provisions of this regulation section do apply to such coverage because the statute contains no exemptions from its reporting requirements for SCHIP coverage offered through premium assistance programs. However, the

regulation does not require States to report encounter data in measuring their progress toward meeting performance goals. We encourage States to use a variety of methods to collect appropriate data. While requiring plans to report encounter data to the State is one means of gathering these data, it is by no means the only method. For example, States can rely on mail or telephone surveys of participating families and surveys of participating providers, or can design a data collection methodology that works with the structure and offerings of their SCHIP programs, including those operating premium assistance programs.

Comment: We received comments recommending that we require specific reporting requirements for States offering premium assistance programs through group health plans.

Response: States that implement or design premium assistance programs for SCHIP have flexibility to explore different methods of working with employers, health plans and beneficiaries to obtain information on SCHIP coverage provided through group health plans. Because of the difficulty of obtaining data from employer plans with which the State may not have direct contractual relationships, we intend to continue to work with States exploring the implementation of premium assistance programs and will continue to consider a variety of State proposals regarding appropriate methods of obtaining information

about the quality of care obtained through premium assistance programs.

Comment: We received comments that the regulation should allow States the flexibility to use strategies that employers already have in place, or to use alternative strategies, to ensure quality and appropriateness of care.

Response: First, it should be noted that, upon further reflection, we have determined that the provisions and intent of proposed §457.735 would fit more appropriately within Subpart D, Benefits. The focus of this provision is to ensure that SCHIP enrollees have adequate access to health care services as needed. Therefore, we have moved the comments and responses on this provision to Subpart D, §457.495.

We agree that, pursuant to the provisions of title XXI, States should have the flexibility to use innovative strategies to ensure quality and appropriateness of care. Section 457.495(a) provides that States must provide HCFA with a description of the methods that a State uses for assuring the quality and appropriateness of care provided under the plan. We did not specify a particular method States must use to monitor appropriateness and quality of care. We anticipate that States will use a variety of methods, including those most suitable for the type of program or programs a particular State is implementing.

Comment: Several commenters recommended that we establish specific, unified, quality and access standards with respect to those areas set forth in §457.495 and identify the methodologies for monitoring those standards in the regulations. Several commenters recommended that we require States to describe methods they will use to ensure that children have access to pediatricians and other health care providers with expertise in meeting the health care needs of children. The commenters felt that physicians who are appropriately educated in the unique physical and developmental issues surrounding the care of infants, children, young adults and adolescents should provide children's care. As the SCHIP program is specifically designed to serve children, commenters noted that it is critical that access to appropriate providers of care be required. One commenter recommended the annual application of a standardized survey of children's mental, physical, and social health.

Response: Section 457.495 requires that a State describe the specific elements of its quality assurance strategies. These may include the use of any of the following methods: quality of care standards; performance measurement, information and reporting strategies, licensing standards, credentialing/recredentialing processes, periodic reviews and external reviews. We are not requiring that States meet specific, unified standards regarding access to and quality of

care. However, the regulation at §457.495 does requires States to assure the quality and appropriateness of care provided under the State plan. As part of the State's assurances, each State agency would be expected to assure that all covered services are available and accessible to program enrollees. This means that all covered services would be available within reasonable time frames and in a manner that ensures continuity of care, adequate primary and specialized services, and access to providers appropriate to the population being served under the SCHIP plan. We believe this assurance is sufficient to address the concerns of the commenters.

Comment: One commenter recommended that quality of care standards reflect professional judgment and local standards of care as distinguished from standards of care developed by third-party payers or fiscal intermediaries.

Response: We encourage States, as they create methods of assuring and evaluating quality of care provided to SCHIP participants, to take into consideration sources of quality of care standards and to make a determination about whether to incorporate standards endorsed or used by local providers, national provider associations, national health research institutes, or health insurance or managed care organizations into their State plan.

Comment: Several commenters supported the requirement in

§457.735(a) that States describe methods of assuring the quality and appropriateness of care under SCHIP, particularly with regard to well-baby and well-child care, immunizations, and access to specialty care. One commenter suggested that HCFA use the phrase "access to specialty services" rather than the phrase "access to specialists" in §457.735(b).

Response: We considered the commenters' suggestion and concluded that modifying the term "access to specialists" with the clarification of "access to specialists experienced in treating the enrolled's medical condition" would provide broader assurances that the children identified in §457.495(c) would have access to the appropriate specialty services. Therefore, we have revised §457.495(c) accordingly.

Comment: We received several comments applauding the inclusion of well-adolescent care with well-child care in the quality assurance requirements at §457.495. Commenters suggested including the word "adolescent" in the definition of well-baby and well-child services and using the term in connection with well-child care throughout the regulation. The commenters indicated that they believe we should focus on the unique health needs of adolescents, which make up approximately 39 percent of SCHIP eligible youth, because their health needs differ from those of younger children. The commenters also urged HCFA to

list specifically in the regulation medical sources that have guidelines for infants, children and adolescents. In these commenters' view, these sources should include the American Academy of Pediatrics' "Guidelines for Health Supervision of Infants, Children and Adolescents," the American Medical Association's "Guidelines for Adolescent Preventive Services," and the American College of Obstetricians and Gynecologists' "Primary and Preventive Health Care for Female Adolescents."

Response: We appreciate the commenters' support of our emphasis on assuring the quality and appropriateness of care for children and our specific reference to certain types of adolescent care. While understand the view that this emphasis is important at §457.495, because of our concern for assuring quality and appropriateness of care, we have not adopted the commenters suggestion with respect to using this terminology throughout the rest of the final rule. The definition of child for purposes of SCHIP at §457.10 and section 2110(c)(1) of the Act indicates that a "child" is an "individual under the age of 19." Adolescents within this age range are clearly included in this definition and therefore we have not included the term in other references to well-baby and well-child care. Because we are not requiring that States adopt specific standards of care, we are not including the commenters' list of sources in the regulation text. We are including the commenters' listing here

in the preamble so that States may consider these sources as recommendations in developing their own standards.

Comment: One commenter noted that accreditation is a method widely used by commercial purchasers to assure the quality of care provided by health plans. The commenter noted that accreditation, a comprehensive assessment of the quality of a health plan, is particularly useful in assessing the effectiveness and timeliness of procedures used to monitor and treat enrollees with serious medical conditions. The commenter urged HCFA to acknowledge that a State using HEDIS (Health Plan Employer Data and Information Set) measures would meet the State plan requirements set forth in this section. The commenter noted that HEDIS includes measures that specifically address the elements of care within SCHIP including:

-- Childhood and adolescent immunizations;

-- Use of appropriate medications for people with asthma;

-- Children's access to primary case managers (PCPs);

-- Annual dental visits;

-- Well child visits in the first 15 months, third, fourth, fifth, and sixth years of life;

-- Adolescent well visits;

-- Ambulatory care;

-- Inpatient utilization;

-- Ratings of personal doctor, nurse, specialist;

-- Rating of health care;

-- Rating of health plan;

-- Getting needed care and getting care quickly;

-- How well doctors communicate;

-- Courteous and helpful staff; and

-- Customer service and claims processing.

Response: States have flexibility in determining the State-specific performance measures they will use in determining quality and access to care. In making these determinations, States have the ability to utilize those data collection tools and analysis methodologies that are most suited to the circumstances of their SCHIP program. HEDIS is one of several tools we recommended in the proposed regulation that States consider as they design ways of measuring appropriateness and quality of care in SCHIP, but there may be other tools States may wish to consider. Specifically, in the preamble to the proposed rule, we recommended that States refer to several tools including the Consumer Assessments of Health Plans Study (CAHPS), the U.S. Preventive Services Task Force Guidelines, Bright Futures: Guidelines for Health Supervision of Infants, Children, and Adolescents, and the Office of Disease Prevention and Health Promotion's Health People 2000 and Healthy People 2010.

Comment: One commenter cautioned HCFA that while HEDIS is a widely accepted and adopted collection system, it has limitations

in its usefulness for monitoring performance under SCHIP. The commenter urged HCFA to work with NCQA to understand these limitations and the explore ways to address them. Additionally, the commenter encouraged HCFA to include the *American Academy of Pediatrics Guide for Health Supervision III* to the list of standards, benchmarks, and guidelines states should look to for performance measures.

Response: We agree that the suggested performance measure guidelines mentioned in the preamble to the proposed rule all have certain limitations that the States should take into consideration as they develop strategies for measuring performance goals related to their strategic objectives. Additionally, we encourage States to consider the *American Academy of Pediatrics Guide for Health Supervision III* in developing their performance measures.

Comment: Commenters recommended that we require States to include procedures to monitor the extent to which the program has sufficient network capacity, including providers and specialists who serve the particular needs of the adolescent enrollees, both male and female, and provides services such as women's health services, family planning and transitional services. According to these commenters, the monitoring should include measures relevant to the care of adolescents, (annual well-adolescent visits, adolescent immunization rates, etc.) and immigrants, and

access to services without unreasonable delay.

Response: We have not adopted the commenters' suggestions. Section 457.495 requires States to include in the State plan a description of the methods that a State uses for assuring the quality and appropriateness of care and for ensuring access to covered services provided under an SCHIP plan. It is therefore, not appropriate to include a list of specific types of services, specialists, or groups; and risk unintentionally excluding an area that also needs attention. However, we did include language regarding access to specialists in general in order to emphasize the need for such access. We have also required States to provide a decision regarding the authorization of health services within 14 days of the service being requested. A possible extension to this 14 day period may be granted in the event that the enrollee requests an extension or the physician or the health plan determines that additional information is required. All such decisions must be made in accordance with the medical needs of the patient. The language of section 457.495 as finalized, allows us to address the concerns of the commenters while allowing States the flexibility the SCHIP statute provides them.

Comment: One commenter indicated that it was difficult to determine the applicability of the requirement to assure appropriate and timely procedures to monitor and treat enrollees

with complex and serious medical conditions for fee-for-service programs. The commenter believed that the quality of care monitoring requirement in §457.495(a) is sufficient to protect enrollees and that the requirement at §457.495(b) regarding complex and serious medical conditions should be eliminated.

Response: We disagree with the commenter. Because of the importance of ensuring that children with chronic, serious or complex medical conditions receive continuous and appropriate care, with the ability to access specialists as often as needed, particular attention is necessary in specifying the requirement at §457.495. We understand that it is more difficult for States to implement this requirement in the fee-for-service sector than it would be in a managed care environment. However, in order to assure quality care to participants with chronic, serious or complex medical conditions, it is essential that States provide specific assurances that they have established appropriate procedures to monitor and treat these participants whether they are enrolled through fee-for-service programs or through MCEs. Therefore, we have retained the requirement at §457.495(b), as revised.

Comment: One commenter urged HCFA to require the States to describe procedures for providing case management to those with complex and serious medical conditions. The commenter believed

that quality of care for those with complex medical conditions is greatly enhanced by case management. The commenter also urged HCFA to require States' to include appropriate peer review by pediatricians and appropriate pediatric specialists in their quality assurance mechanism.

Response: While States may want to establish procedures for providing case management to enrollees with chronic, complex or serious medical conditions to enhance quality and access to care for those participants, we have not required all States to use that particular method to assure quality and appropriateness of care. We note that case management is one service that States may, but are not required to, provide under '457.402. However, other methods to assure quality and appropriate care are also acceptable and may be just as effective, depending upon the design of the State’s SCHIP.

Comment: One commenter suggested that we revise §457.495(b) as follows: "States must assure appropriate and timely procedures to monitor and treat enrollees with complex, serious or chronic medical conditions (including symptoms) including access to appropriate pediatric, adolescent and other specialists and specialty care centers and must assure that children with complex, serious or chronic medical conditions receive no lower quality of care than received by children with special health care needs served by the State's programs under title V of the

Social Security Act.”

Response: We will modify the phrase “complex and serious”, to add the term “chronic”, as suggested by the commenter. In addition, to provide further flexibility, we are changing the word “and” to “or”; and the phrase will be written as, “chronic, complex or serious”. We believe this phrase encompasses the symptoms of these enrollees, making further specification unnecessary. We have also revised the requirement for access to specialists within that provision to read, “access to specialists experienced in treating the specific medical condition...” We believe the addition of these terms in §457.495(b) assures that SCHIP programs will adequately serve the health needs of enrollees with chronic, complex or serious medical conditions, by assuring that children with these conditions will have access to care from specialists most adequately suited to meet the child’s needs. Since States have the flexibility to establish their own standards for assuring appropriate treatment and quality of care, we do not agree with the commenter’s suggestion that we should specify the inclusion of specialty care centers or particular standards of care.

Comment: One commenter mentioned several times throughout its comments that access to dental services is a problem under Medicaid and that HCFA should take action to correct this problem.

Response: While Medicaid coverage of dental services is not the subject of this regulation, we would like to bring to the attention of the commenter the HCFA/HRSA Oral Health Initiative (OHI) which is an ongoing effort to improve access to high quality oral health services for vulnerable populations, particularly children enrolled in Medicaid and SCHIP. HCFA teamed with HRSA almost two years ago and initiated the OHI in a effort to bring together Federal staff, State Medicaid agencies and national, State and local level dental organizations to recognize and address this issue. Both HCFA and HRSA recognize that resolving barriers to oral health access in Medicaid and SCHIP must begin with the understanding that Medicaid and SCHIP are programs that rely upon Federal-State partnerships: the Federal government provides broad guidelines under which States implement individual programs. Both HCFA and HRSA believe that solutions to oral health disparity in Medicaid and SCHIP will most likely be found at the local and State levels. Both agencies seek to provide resources, guidance and technical assistance necessary to enable States and localities to better address their local oral health concerns.

Some activities that have been undertaken by the OHI include: co-sponsoring a national leadership conference that brought together for the first time the State Medicaid and State Dental Directors with the leadership of the dental profession;

collaborating with the private sector (that is, the American Dental Association convened a second national leadership conference for stakeholders to continue the progress and dialogue achieved in the first meeting and also to include State legislators in the process); supporting State dental summits/workshops to provide the opportunity for State level players to meet with each other on a face-to-face basis to address oral health problems specific to their States and develop State-specific strategies and implementation plans; promoting best practices by providing State dental officials the opportunity to share common dental concerns and potential best practices by initiating and supporting a privately managed electronic list serve which connects, for the first time, Medicaid program officials in each State with each other, and with State health officials and the Federal OHI team. Discussion of further activities undertaken by HCFA and the OHI to improve the oral health of this vulnerable population is contained in the Department responses to the April 27, 1999 report of the General Accounting Office (GAO), “Oral Health: Dental Disease is a Chronic Problem Among Low-Income Populations.” This report is available from the GAO web site at www.gao.gov.

Finally, in an effort to focus attention on the oral health issues and to build an oral health infrastructure, HCFA has appointed a full-time Chief Dental Officer to serve as a focal

point for oral health issues and has identified staff in each HCFA Regional Office to serve as Medicaid dental coordinators.

Comment: Several commenters suggested that the regulation include language to specifically require access to various types of providers, such as, pediatric and adolescent specialists, and obstetricians/gynecologists. In addition, one commenter suggested that State plans should be required to assure that female adolescents have direct access to women's health specialists and that pregnant adolescents be permitted to continue seeing their treating provider through pregnancy and the post-partum period in instances where the contracting plan or provider has left the SCHIP program.

Response: We have not adopted the commenters' suggestions. Section 457.495 requires that the State plan include assurances of the quality and appropriateness of care and services provided under a State plan including treatment of chronic, serious or complex medical conditions and access to specialists. This requirement addresses the concerns of the commenters while allowing States the flexibility to establish the means by which they will assure access to appropriate care that the SCHIP program provides them. This regulation requires States to ensure access to providers appropriate to the population being served under the State plan.

Comment: Two commenters recommended that we revise the

regulation to provide that a State and its participating contractors must provide services as expeditiously as the enrollee's health condition requires. The commenter also suggested time frames of approval of a request for services within seven calendar days after receipt of the request for services, with a possible extension of fourteen days. The commenters also recommended an expedited time frame if the physician indicates, or the State/contractor determines that following ordinary time frames could seriously jeopardize the enrollee's life or health or ability to regain maximum function, to be no later than 72 hours after receipt of the request for services, with a possible extension of up to 14 additional calendar days. Another commenter suggested requiring a response within seven days to an initial request for service or within 72 hours for an expedited procedure.

Response: We recognize the commenters' concerns and have addressed these issues in new subpart K, Applicant and Enrollee Protections, at §457.1160.